APR 10 2009

510(k) SUMMARY

ConMed Linvatec Paladin™, Preloaded with two #2 Hi-Fi® Sutures

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for the 510(k) Number K090186.

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Joy Lovett
Regulatory Affairs Specialist
(727) 399-5137 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name:	ConMed Linvatec Paladin, Preloaded with two #2 Hi-Fi® Sutures
Common Name:	Bioabsorbable suture anchor
Classification Name:	Biodegradable soft tissue fixation fastener
Proposed Class/Device:	Class II
Product Code:	MAI
Regulation:	21 CFR Part 888.3030

D. Predicate/Legally Marketed Devices

Device Name:	ConMed Linvatec Duet Suture Anchor
Company Name:	ConMed Linvatec
510(k) #:	K042966
Device Name:	ConMed Linvatec Bio Mini-Revo Suture Anchor
Company Name:	ConMed Linvatec
510(k) #:	K053561

E. Device Description

The *ConMed Linvatec Paladin Suture Anchor* is a bioabsorbable screw-in suture anchor that is preloaded on a disposable inserter device with two non-absorbable, braided, polyethylene sutures. The *ConMed Linvatec Paladin Suture Anchor* is manufactured from Self-Reinforced (96L/4D) PLA Copolymer. The copolymer is inert and non-collagenous through the absorption process. The device will be available in 5.0mm - 6.5mm in size with colorant D&C violet #2.

F. Intended Use/ Indications

The device may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules, to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

G. Substantial Equivalence

The ConMed Linvatec Paladin Suture Anchor is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the identified predicate devices K042966 and K053561.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ConMed Livatec
% Ms. Joy Lovett
Regulatory Affairs Specialist
11311 Concept Boulevard
Largo, Florida 33773-4908

APR 10 2009

Re: K090186
Trade/Device Name: ConMed Linvatec Paladin, Preloaded with tow #2 Hi-Fi Sutures
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI
Dated: March 12, 2009
Received: March 13, 2009

Dear Ms. Lovett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090186

Device Name: *ConMed Linvatec Paladin, Preloaded with two #2 Hi-Fi Sutures*

Indications for Use:

The device may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use_____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Murray for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090186